REMARKS

Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

I. Status of the Claims

Claims 1-20 and 22-26 are pending.

Claims 9-16 were previously withdrawn in response to the Restriction Requirement dated May 28, 2008.

Claim 21 was previously cancelled.

Claims 27-34 have been added.

Thus, claims 1-8, 17-20, and 22-34 are currently being examined.

No new matter has been added.

II. Acknowledgement of Allowed Claims

Applicants note with gratitude the Examiner's allowance of claims 17-20.

III. Claim Rejections – 35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 1-8, 22, and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse.

Claim 1 has been amended to recite the method of using the device of claim 17 to minimize the likelihood of false-positive and false-negative results in the detection of small amounts of amniotic fluid in a vaginal secretion of a pregnant woman. As the device claim 17 is found to be allowable, this amendment puts claim 1 in condition for allowance. As claims 2-8 depend from claim 1, claims 2-8 are also in condition for allowance.

The Examiner states that claim 22 and 24 are vague because the claims are not clear as to how the ratio of the antibodies on the solid support provides a threshold level of detection of

PAMG-1 of either 5 nanograms per milliliter or above 3 nanograms. The Examiner contends that because only one marker is being used, the binding of PAMG-1 to the different antibodies in the capture section cannot be distinguished to generate a ratio. The Examiner also contends that the claims are not clear as to how the 5 or 3 ng/ml threshold concentration was chosen.

Claims 22 and 24 have been amended to clarify that the antibodies are present in an optimal concentration to provide an appropriate sensitivity threshold level of detection of PAMG-1 to prevent a false positive result due to inflammation exudate. As demonstrated in Example 9.2 of the Specification, varying the concentrations of the immobilized antibodies produces different optical densities within the test band. Thus, the concentrations of immobilized antibodies can be selected to produce a response within the appropriate test range. As discussed in the Specification (page 8, lines 18-21) the most appropriate sensitivity threshold level of the method is found to be close to 5 ng/ml since the upper level of PAMG-1 in vaginal secretion, which may be due to inflammation caused by vaginitis, does not exceed 3 ng/ml. *See also* Specification page 37, lines 15-21; Example 8; and Tables 10 and 11 which shows data of PAMG-1 secretions in women with vaginitis. Therefore, the concentration of the immobilized antibodies of the present invention are such that the PAMG-1 levels will be detected when they have reached 5 ng/ml or when they have reached an excess of 3 ng/ml.

Accordingly, Applicants respectfully requests the withdrawal of this rejection for claims 1-8, 22, and 24.

IV. Claim Rejections – 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 23, 25, and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse.

The Examiner states that while it appears that the antibodies have been deposited, it is not clear from the Specification whether all the provisions of the Budapest Treaty have been followed.

Submitted with this response is a Declaration of Michael Friedman Regarding Microorganism Deposits in Accordance with 37 C.F.R. §§ 1.801-1.809, demonstrating that the antibodies were properly deposited under the provisions of the Budapest Treaty.

Accordingly, Applicants respectfully requests the withdrawal of this rejection for claims 1-23, 25, and 26.

IV. New Claims

Claims 27-34 have been added which depend from allowed claim 17. The support for such claims can be found, for example, in the Specification at page 9, lines 19-26 and page 33, line 13-page 35, line 2. No new subject matter has been added.

CONCLUSION

In view of the above amendments and remarks, it is believed that the claims are in condition for allowance and it is respectfully requested that the case be passed to issue.

Applicants reserve the right to pursue the cancelled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: May 19, 2009

Respectfully submitted,

By _____

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